

Exhibit C

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Attorneys for Defendants C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS C. R. BARD, INC.'S
AND BARD PERIPHERAL
VASCULAR, INC.'S RESPONSES
AND OBJECTIONS TO
PLAINTIFFS' NOTICE OF
DEPOSITION PURSUANT TO
FEDERAL RULE OF CIVIL
PROCEDURE 30(B)(6) AND
RELATED REQUESTS FOR
PRODUCTION OF DOCUMENTS**

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively referred to herein as "Bard"), by and through counsel, respond to Plaintiffs' Notice of Deposition Pursuant to Federal Rule of Civil Procedure 30(b)(6) and Related Requests for Production of Documents, served on November 5, 2015 ("Notice"), as follows:

SUBJECT MATTER IDENTIFIED IN EXHIBIT “A”**TOPIC NO. 1:**

All communications with FDA officials regarding the subject matter and content of the warning letter issued by FDA on July 13, 2015 including but not limited to communications described in the letter.

RESPONSE:

Bard will produce a witness to testify generally concerning Bard’s communications with FDA officials regarding the subject matter and content of the FDA’s July 13, 2015 Warning Letter (the “Letter”).

TOPIC NO. 2:

The identity of BARD’s corporate officers and other employees (including but not limited to their titles, duties and dates of such responsibility) who were and are responsible for communicating with regulatory officials with the FDA and related regulatory bodies concerning the subject matter and content of the warning letter issued by FDA on July 13, 2015.

RESPONSE:

Bard will produce a witness to testify generally concerning the identity of the individuals responsible for communicating with applicable regulatory bodies concerning the subject matter of the Letter.

TOPIC NO. 3:

The visits/inspections from/by the FDA to Bard facilities on the dates listed in the warning letter issued by the FDA on July 13, 2015.

RESPONSE:

Bard will produce a witness to testify generally concerning the FDA inspections and visits discussed in the Letter.

TOPIC NO. 4:

The failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints associated with Bard’s IVC filters and Bard IVC filter removal products as described in the warning letter issued by the FDA on July 13, 2015.

RESPONSE:

Bard objects to this Topic as argumentative to the extent it assumes, as fact, that Bard “fail[ed] to establish and maintain procedures for receiving, reviewing, and

1 evaluating complaints.” Although Bard is aware that the Letter contains such language,
2 Bard contests that any such failure occurred as stated in the Letter.

3 Subject to the foregoing objection, Bard states that it will produce a witness to
4 testify generally concerning Bard’s procedures for receiving, reviewing, and evaluating
5 complaints associated with its IVC filters and the claims made by FDA in the Letter
6 regarding the same.

7 **TOPIC NO. 5:**

8 **Determination of lot numbers subject to the failure to establish and maintain**
9 **procedures for acceptance of incoming product as described in paragraph 5 of the**
10 **warning letter issued by the FDA on July 13, 2015.**

11 **RESPONSE:**

12 Bard objects to this Topic as argumentative to the extent it assumes, as fact, that
13 Bard “fail[ed] to establish and maintain procedures for acceptance of incoming product.”
14 Although Bard is aware that the Letter contains such language, Bard contests that any
15 such failure occurred as stated in the Letter.

16 Subject to the foregoing objection, Bard states that it will produce a witness to
17 testify generally concerning Bard’s procedures for the acceptance of incoming product
18 from suppliers as discussed in Paragraph 5 of the Letter, and the claims made by FDA in
19 the letter regarding the same. By way of further response, Bard notes that the Letter
20 delineates the specific lot numbers that are at issue in the Letter, and Bard will produce a
21 witness to testify generally concerning how those lot numbers were identified.

22 **TOPIC NO. 6:**

23 **The failure to submit reports as described in paragraph 7 of the warning**
24 **letter issued by the FDA on July 13, 2015 and the responses submitted by Bard to the**
25 **FDA listed as inadequate.**

26 **RESPONSE:**

27 Bard objects to this Topic as argumentative to the extent it assumes, as fact, that
28 Bard “fail[ed]” to submit MDR reports to the FDA. While Bard acknowledges that the
Letter identifies four complaints that Bard received for which Bard did not initially submit
MDRs to the FDA, this alleged violation stated in Paragraph 7 of the Letter is an isolated

1 incident that is not indicative of Bard's overall adverse event reporting practices and
2 procedures.

3 Subject to the foregoing objection, Bard states that it will produce a witness to
4 testify generally concerning Bard's adverse event reporting practices and procedures,
5 Bard's actions and reporting concerning the four complaints identified in Paragraph 7 of
6 the Letter, FDA's claims regarding the same as stated in Paragraph 7 of the Letter, and
7 Bard's responses to the FDA concerning Paragraph 7 of the Letter.

8 **TOPIC NO. 7:**

9 **Actions taken by Defendants since the issuance of the warning letter issued by
10 FDA on July 13, 2015.**

11 **RESPONSE:**

12 Bard objects to this Topic on the grounds that it is overly broad and unduly
13 burdensome in that, taken literally, it seeks an individual who can testify regarding every
14 single "action" taken by Bard since July 13, 2015. Bard further objects to this Topic on
15 the grounds that its use of the term "actions" without any additional context is vague and
16 ambiguous and subject to varying interpretations. Finally, Bard objects to this Topic to the
17 extent it seeks information that is subject to the attorney-client privilege, work-product
18 doctrine, or any other applicable privilege or immunity.

19 Subject to the foregoing objection, Bard states that it will produce a witness to
20 testify generally concerning the communications that Bard has had with the FDA
21 regarding the Letter after July 13, 2015, Bard's commitments to take certain steps to
22 address the issues raised by the FDA in the Letter, FDA responses to such commitments,
23 and the steps that Bard has taken to and plans to take to address the issues raised by the
24 FDA in the Letter.

25 **REQUESTS FOR PRODUCTION IDENTIFIED IN EXHIBIT "B"**

26 **REQUEST NO. 1:**

27 **An unredacted and final copy of the warning letter issued by FDA on July 13,
28 2015 to Bard.**

RESPONSE:

Bard has produced to the plaintiffs a copy of the FDA's July 13, 2015 Warning Letter to Bard. Said document was produced at Bates number BPV-17-01-00204231 through BPV-17-01-00204243.

REQUEST NO. 2:

All communications with FDA related to the subject matter of the warning letter issued by the FDA on July 13, 2015.

RESPONSE:

Bard objects to this Request as vague and ambiguous with respect to the term "related to the subject matter of the warning letter issued by the FDA on July 13, 2015." Taken literally, this Request could be interpreted as demanding production of all communications that Bard has ever had with the FDA regarding any of its IVC filters and/or the Recovery® Cone, regardless of whether such communications are directly related to the Letter. Additionally, such a Request is overly broad because it exceeds the scope of allowable discovery under the Court's October 30, 2015 Case Management Order No. 2 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard offered to produce all communications with the FDA concerning the FDA's 483 Letters and Warning Letter, including Bard's responses to the same. Bard further proposed to produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated that, after such discovery, the parties could meet and confer regarding any additional discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel during the October 29, 2015 Case Management Conference stated that Bard would produce all "communications back and forth between Bard and the [FDA] beginning with the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr.

1 120:7-10 (Oct. 29, 2015). Although the plaintiffs’ counsel asked the Court for a broader
 2 production, *see id.* at 122:4 - 123:18, the Court agreed with Bard’s proposal. Indeed, the
 3 Court’s October 30, 2015 CMO No. 2 orders Bard to produce “the documents described
 4 by defense counsel during the case management conference related to the FDA
 5 investigation and warning letter.” CMO No. 2, at p.3 (Oct. 30, 2015). It further provides
 6 that the plaintiffs may “take a Rule 30(b)(6) deposition with respect to the FDA
 7 investigation and warning letter” by January 16, 2016. *Id.* All other discovery in this MDL
 8 has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a “Second Phase of
 9 Discovery,” during which the parties must meet and confer and may seek, among other
 10 things, “[f]urther discovery related to the FDA inspection and warning letter.” Thus, the
 11 Court’s CMO No. 2 contemplates an initial, defined approach to discovery regarding the
 12 FDA’s 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless
 13 approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request
 14 exceeds the parameters of discovery ordered by the Court.

15 Notwithstanding the foregoing, Bard notes that it has previously produced to the
 16 plaintiffs Bard’s 510(k) submissions and associated official correspondence files for its
 17 retrievable IVC filters, including the Recovery®, G2®, G2® Express, Eclipse®, and
 18 Meridian® Filters. Said documents are categorized and listed by Bates number on the
 19 index provided by Bard to the plaintiffs’ counsel on November 20, 2015.

20 In light of the foregoing objections, Bard states that, in accordance with the Court’s
 21 CMO No. 2, it has searched for and produced to the plaintiffs copies of all of Bard’s
 22 written communications to and from the FDA concerning the FDA’s November 25, 2014
 23 and January 5, 2015 483 Letters to Bard, and FDA’s July 13, 2015 Warning Letter to
 24 Bard. The timeframe of communications that Bard searched and produced spans from
 25 October 2014 through December 3, 2015. Said documents have been produced at Bates
 26 numbers BPV-17-01-00193330 through BPV-17-01-00204480 and BPV-17-01-00205165
 27 through BPV-17-01-00206171, and Bard notes that it provided the plaintiffs with a
 28 comprehensive index of said documents on November 16, 2015, and supplemental indices

1 on December 2, 2015, and December 3, 2015. Finally, Bard states that it has not searched
2 for nor is producing any documents in response to this Request beyond those identified
3 via the aforementioned search parameters.

4 **REQUEST NO. 3:**

5 **All documents which reflect a regulatory log of contacts with the FDA**
6 **regarding the warning letter issued by FDA on July 13, 2015.**

7 **RESPONSE:**

8 Bard has produced to the plaintiffs a copy of its FDA Contact Log concerning
9 communications regarding the FDA's July 13, 2015 Warning Letter. The Contact Log was
10 produced at Bates number BPV-17-01-00200590.

11 **REQUEST NO. 4:**

12 **All complaint files referenced in the warning letter issued by FDA on July 13,**
13 **2015.**

14 **RESPONSE:**

15 Bard objects to this Request as overly broad because it exceeds the scope of
16 allowable discovery under the Court's October 30, 2015 Case Management Order No. 2
17 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently
18 stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard
19 offered to produce all communications with the FDA concerning the FDA's 483 Letters
20 and Warning Letter, including Bard's responses to the same. Bard further proposed to
21 produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the
22 plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated
23 that, after such discovery, the parties could meet and confer regarding any additional
24 discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's
25 understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was
26 amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel
27 during the October 29, 2015 Case Management Conference stated that Bard would
28 produce all "communications back and forth between Bard and the [FDA] beginning with
the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr.

120:7-10 (Oct. 29, 2015). Although the plaintiffs’ counsel asked the Court for a broader production, *see id.* at 122:4 - 123:18, the Court agreed with Bard’s proposal. Indeed, the Court’s October 30, 2015 CMO No. 2 orders Bard to produce “the documents described by defense counsel during the case management conference related to the FDA investigation and warning letter.” CMO No. 2, at p.3 (Oct. 30, 2015). It further provides that the plaintiffs may “take a Rule 30(b)(6) deposition with respect to the FDA investigation and warning letter” by January 16, 2016. *Id.* All other discovery in this MDL has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a “Second Phase of Discovery,” during which the parties must meet and confer and may seek, among other things, “[f]urther discovery related to the FDA inspection and warning letter.” Thus, the Court’s CMO No. 2 contemplates an initial, defined approach to discovery regarding the FDA’s 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request exceeds the parameters of discovery ordered by the Court.

On the basis of its objections, Bard states that it has not searched for nor is producing in response to this Request any documents.

REQUEST NO. 5:

All complaint files provided to and/or reviewed by FDA as part of the investigation and inspections that resulted in the warning letter issued by FDA on July 13, 2015.

RESPONSE:

Bard objects to this Request as overly broad because it exceeds the scope of allowable discovery under the Court’s October 30, 2015 Case Management Order No. 2 (“CMO No. 2”), as well as it exceeds the scope of the discovery that Bard has consistently stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard offered to produce all communications with the FDA concerning the FDA’s 483 Letters and Warning Letter, including Bard’s responses to the same. Bard further proposed to produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the plaintiffs’ Notice, which the plaintiffs had previously provided to Bard. Bard then stated

1 that, after such discovery, the parties could meet and confer regarding any additional
 2 discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's
 3 understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was
 4 amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel
 5 during the October 29, 2015 Case Management Conference stated that Bard would
 6 produce all "communications back and forth between Bard and the [FDA] beginning with
 7 the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr.
 8 120:7-10 (Oct. 29, 2015). Although the plaintiffs' counsel asked the Court for a broader
 9 production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the
 10 Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described
 11 by defense counsel during the case management conference related to the FDA
 12 investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides
 13 that the plaintiffs may "take a Rule 30(b)(6) deposition with respect to the FDA
 14 investigation and warning letter" by January 16, 2016. *Id.* All other discovery in this MDL
 15 has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a "Second Phase of
 16 Discovery," during which the parties must meet and confer and may seek, among other
 17 things, "[f]urther discovery related to the FDA inspection and warning letter." Thus, the
 18 Court's CMO No. 2 contemplates an initial, defined approach to discovery regarding the
 19 FDA's 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless
 20 approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request
 21 exceeds the parameters of discovery ordered by the Court.

22 This Request is also overly broad, unduly burdensome, and disproportionate to the
 23 needs of the case, given the vast expansiveness of the Request (which demands production
 24 of all complaint files "reviewed by FDA as part of the investigation and inspections"),
 25 particularly considering that the issues raised by the FDA in its 483 Letters and FDA
 26 Warning Letter have little or no relevance in this litigation. Bard further objects to this
 27 Request because it seeks information or material that is outside of Bard's possession,
 28 custody, or control, to the extent it seeks materials "reviewed by FDA." Bard notes that it

1 does not know the precise documents or materials reviewed by FDA during its
2 investigation and inspections.

3 On the basis of its objections, Bard states that it has not searched for nor is
4 producing in response to this Request any documents.

5 **REQUEST NO. 6:**

6 **All documents and materials provided to and/or reviewed by FDA as part of**
7 **the investigation and inspections that resulted in the warning letter issued by FDA**
8 **on July 13, 2015.**

8 **RESPONSE:**

9 Bard objects to this Request as overly broad because it exceeds the scope of
10 allowable discovery under the Court's October 30, 2015 Case Management Order No. 2
11 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently
12 stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard
13 offered to produce all communications with the FDA concerning the FDA's 483 Letters
14 and Warning Letter, including Bard's responses to the same. Bard further proposed to
15 produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the
16 plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated
17 that, after such discovery, the parties could meet and confer regarding any additional
18 discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's
19 understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was
20 amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel
21 during the October 29, 2015 Case Management Conference stated that Bard would
22 produce all "communications back and forth between Bard and the [FDA] beginning with
23 the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr.
24 120:7-10 (Oct. 29, 2015). Although the plaintiffs' counsel asked the Court for a broader
25 production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the
26 Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described
27 by defense counsel during the case management conference related to the FDA
28 investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides

1 that the plaintiffs may “take a Rule 30(b)(6) deposition with respect to the FDA
2 investigation and warning letter” by January 16, 2016. *Id.* All other discovery in this MDL
3 has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a “Second Phase of
4 Discovery,” during which the parties must meet and confer and may seek, among other
5 things, “[f]urther discovery related to the FDA inspection and warning letter.” Thus, the
6 Court’s CMO No. 2 contemplates an initial, defined approach to discovery regarding the
7 FDA’s 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless
8 approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request
9 exceeds the parameters of discovery ordered by the Court.

10 This Request is also overly broad, unduly burdensome, and disproportionate to the
11 needs of the case, given the vast expansiveness of the Request (which demands production
12 of all documents and materials “reviewed by FDA as part of the investigation and
13 inspections”), particularly considering that the issues raised by the FDA in its 483 Letters
14 and FDA Warning Letter have little or no relevance in this litigation. Bard further objects
15 to this Request because it seeks information or material that is outside of Bard’s
16 possession, custody, or control, to the extent it seeks materials “reviewed by FDA.” Bard
17 notes that it does not know the precise documents or materials reviewed by FDA during
18 its investigation and inspections.

19 In light of the foregoing objections, Bard states that, in accordance with the Court’s
20 CMO No. 2, it has searched for and produced to the plaintiffs copies of all of Bard’s
21 written communications to and from the FDA concerning the FDA’s November 25, 2014
22 and January 5, 2015 483 Letters to Bard, and FDA’s July 13, 2015 Warning Letter to
23 Bard. The timeframe of communications that Bard searched and produced spans from
24 October 2014 through December 3, 2015. Said documents have been produced at Bates
25 numbers BPV-17-01-00193330 through BPV-17-01-00204480 and BPV-17-01-00205165
26 through BPV-17-01-00206171, and Bard notes that it provided the plaintiffs with a
27 comprehensive index of said documents on November 16, 2015, and supplemental indices
28 on December 2, 2015, and December 3, 2015. Finally, Bard states that it has not searched

1 for nor is producing any documents in response to this Request beyond those identified
2 via the aforementioned search parameters.

3 **REQUEST NO. 7:**

4 **All internal communications relating to the subject matter of the warning**
5 **letter issued by FDA on July 13, 2015.**

6 **RESPONSE:**

7 Bard objects to this Request as overly broad because it exceeds the scope of
8 allowable discovery under the Court's October 30, 2015 Case Management Order No. 2
9 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently
10 stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard
11 offered to produce all communications with the FDA concerning the FDA's 483 Letters
12 and Warning Letter, including Bard's responses to the same. Bard further proposed to
13 produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the
14 plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated
15 that, after such discovery, the parties could meet and confer regarding any additional
16 discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's
17 understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was
18 amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel
19 during the October 29, 2015 Case Management Conference stated that Bard would
20 produce all "communications back and forth between Bard and the [FDA] beginning with
21 the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr.
22 120:7-10 (Oct. 29, 2015). Although the plaintiffs' counsel asked the Court for a broader
23 production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the
24 Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described
25 by defense counsel during the case management conference related to the FDA
26 investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides
27 that the plaintiffs may "take a Rule 30(b)(6) deposition with respect to the FDA
28 investigation and warning letter" by January 16, 2016. *Id.* All other discovery in this MDL

1 has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a “Second Phase of
2 Discovery,” during which the parties must meet and confer and may seek, among other
3 things, “[f]urther discovery related to the FDA inspection and warning letter.” Thus, the
4 Court’s CMO No. 2 contemplates an initial, defined approach to discovery regarding the
5 FDA’s 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless
6 approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request
7 exceeds the parameters of discovery ordered by the Court.

8 This Request is also overly broad, unduly burdensome, and disproportionate to the
9 needs of the case, given the vast expansiveness of the Request (which demands production
10 of all internal communications “relating to the subject matter of the warning letter”),
11 particularly considering that the issues raised by the FDA in its 483 Letters and FDA
12 Warning Letter have little or no relevance in this litigation. This Request is also
13 objectionable as vague, ambiguous, and subject to varying interpretations with respect to
14 the phrase “relating to the subject matter of the warning letter.” Taken literally, this
15 Request could be interpreted as demanding production of all documents that “relate” to
16 any Bard IVC filter, Bard’s complaint handling practices and procedures (regardless of
17 what product is at issue), Bard’s manufacturing processes, controls, and inspections
18 (again, regardless of what product is at issue), and other broad topics that are “related to”
19 the FDA’s Warning Letter. Finally, Bard objects to this Request to the extent it seeks
20 documents that are subject to the attorney-client privilege, work-product doctrine, or any
21 other applicable privilege or immunity.

22 On the basis of its objections, Bard states that it has not searched for nor is
23 producing in response to this Request any documents.

24 **REQUEST NO. 8:**

25 **Communications with FDA and internally since the issuance of the warning**
26 **letter issued by FDA on July 13, 2015 which pertain to the subject matter and**
content of said warning letter.

27 **RESPONSE:**

28 Bard objects to this Request to the extent it seeks “internal[]” communications, on

the grounds that such a Request is as overly broad because it exceeds the scope of allowable discovery under the Court's October 30, 2015 Case Management Order No. 2 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard offered to produce all communications with the FDA concerning the FDA's 483 Letters and Warning Letter, including Bard's responses to the same. Bard further proposed to produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated that, after such discovery, the parties could meet and confer regarding any additional discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel during the October 29, 2015 Case Management Conference stated that Bard would produce all "communications back and forth between Bard and the [FDA] beginning with the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr. 120:7-10 (Oct. 29, 2015). Although the plaintiffs' counsel asked the Court for a broader production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described by defense counsel during the case management conference related to the FDA investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides that the plaintiffs may "take a Rule 30(b)(6) deposition with respect to the FDA investigation and warning letter" by January 16, 2016. *Id.* All other discovery in this MDL has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a "Second Phase of Discovery," during which the parties must meet and confer and may seek, among other things, "[f]urther discovery related to the FDA inspection and warning letter." Thus, the Court's CMO No. 2 contemplates an initial, defined approach to discovery regarding the FDA's 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request

1 exceeds the parameters of discovery ordered by the Court.

2 This Request is also overly broad, unduly burdensome, and disproportionate to the
3 needs of the case, given the vast expansiveness of the Request (which demands production
4 of all internal communications “which pertain to the subject matter and content of said
5 warning letter”), particularly considering that the issues raised by the FDA in its 483
6 Letters and FDA Warning Letter have little or no relevance in this litigation. Finally, Bard
7 objects to this Request to the extent it seeks documents that are subject to the attorney-
8 client privilege, work-product doctrine, or any other applicable privilege or immunity.

9 In light of the foregoing objections, Bard states that, in accordance with the Court’s
10 CMO No. 2, it has searched for and produced to the plaintiffs copies of all of Bard’s
11 written communications to and from the FDA concerning the FDA’s November 25, 2014
12 and January 5, 2015 483 Letters to Bard, and FDA’s July 13, 2015 Warning Letter to
13 Bard. The timeframe of communications that Bard searched and produced spans from
14 October 2014 through December 3, 2015. Said documents have been produced at Bates
15 numbers BPV-17-01-00193330 through BPV-17-01-00204480 and BPV-17-01-00205165
16 through BPV-17-01-00206171, and Bard notes that it provided the plaintiffs with a
17 comprehensive index of said documents on November 16, 2015, and supplemental indices
18 on December 2, 2015, and December 3, 2015. Finally, Bard states that it has not searched
19 for nor is producing any documents in response to this Request beyond those identified
20 via the aforementioned search parameters.

21 **REQUEST NO. 9:**

22 **Documents reflecting actions taken by defendants as a result of the warning**
23 **letter issued by FDA on July 13, 2015.**

24 **RESPONSE:**

25 Bard objects to this Request as overly broad because it exceeds the scope of
26 allowable discovery under the Court’s October 30, 2015 Case Management Order No. 2
27 (“CMO No. 2”), as well as it exceeds the scope of the discovery that Bard has consistently
28 stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard

1 offered to produce all communications with the FDA concerning the FDA's 483 Letters
 2 and Warning Letter, including Bard's responses to the same. Bard further proposed to
 3 produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the
 4 plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated
 5 that, after such discovery, the parties could meet and confer regarding any additional
 6 discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's
 7 understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was
 8 amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel
 9 during the October 29, 2015 Case Management Conference stated that Bard would
 10 produce all "communications back and forth between Bard and the [FDA] beginning with
 11 the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr.
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 13 production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the
 14 Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described
 15 by defense counsel during the case management conference related to the FDA
 16 investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides
 17 that the plaintiffs may "take a Rule 30(b)(6) deposition with respect to the FDA
 18 investigation and warning letter" by January 16, 2016. *Id.* All other discovery in this MDL
 19 has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a "Second Phase of
 20 Discovery," during which the parties must meet and confer and may seek, among other
 21 things, "[f]urther discovery related to the FDA inspection and warning letter." Thus, the
 22 Court's CMO No. 2 contemplates an initial, defined approach to discovery regarding the
 23 FDA's 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless
 24 approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request
 25 exceeds the parameters of discovery ordered by the Court.

26 This Request is also overly broad, unduly burdensome, and disproportionate to the
 27 needs of the case, given the vast expansiveness of the Request (which demands production
 28 of documents "reflecting" "actions taken by defendants as a result of the warning letter"),

1 particularly considering that the issues raised by the FDA in its 483 Letters and FDA
2 Warning Letter have little or no relevance in this litigation. Bard further objects to this
3 Request on the grounds that its use of the term “actions” without any additional context is
4 vague and ambiguous and subject to varying interpretations. Finally, Bard objects to this
5 Request to the extent it seeks documents that are subject to the attorney-client privilege,
6 work-product doctrine, or any other applicable privilege or immunity.

7 In light of the foregoing objections, Bard states that, in accordance with the Court’s
8 CMO No. 2, it has searched for and produced to the plaintiffs copies of all of Bard’s
9 written communications to and from the FDA concerning the FDA’s November 25, 2014
10 and January 5, 2015 483 Letters to Bard, and FDA’s July 13, 2015 Warning Letter to
11 Bard. The timeframe of communications that Bard searched and produced spans from
12 October 2014 through December 3, 2015. Said documents have been produced at Bates
13 numbers BPV-17-01-00193330 through BPV-17-01-00204480 and BPV-17-01-00205165
14 through BPV-17-01-00206171, and Bard notes that it provided the plaintiffs with a
15 comprehensive index of said documents on November 16, 2015, and supplemental indices
16 on December 2, 2015, and December 3, 2015. Said documents include materials that
17 reflect the steps taken by Bard in response the FDA’s July 13, 2015 Warning Letter.
18 Finally, Bard states that it has not searched for nor is producing any documents in
19 response to this Request beyond those identified via the aforementioned search
20 parameters.

21 **REQUEST NO. 10:**

22 **Observations noted on FDA Forms 483, Lists of Inspectional Observations**
23 **that were issued to you at the close of the FDA’s inspections that are referenced in**
24 **the warning letter issued by FDA on July 13, 2015.**

24 **RESPONSE:**

25 Bard has produced copies of FDA’s November 25, 2014 and January 5, 2015 483
26 Letters to Bard. Said documents were produced at Bates numbers BPV-17-01-00193330
27 through BPV-17-01-00193336, and BPV-17-01-00193349 through BPV-17-01-00193358.
28

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1 This 3rd day of December, 2015.

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24 **Bard Peripheral Vascular, Inc.**

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the above and foregoing has been served by First Class postage prepaid U.S. Mail on December 3, 2015, to the following:

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